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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:) Docket No.: 4179-126
Applicant: Tilak M. Shah) Conf. No.: 2458
Application No.: 10/633,238) Art Unit: 3728
Date Filed: August 1, 2003) Examiner: FIDEI, David
Title: PRESS-FLAT CENTRIFUGE TUBE AND SPECIMEN COLLECTION ASSEMBLY COMPRISING SAME) Customer No.: 23448

FACSIMILE TRANSMISSION CERTIFICATE

ATTN: Examiner David Fidei
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Number of Pages (including cover)

Steven J. Hultquist

May 16, 2005

Date

**RESPONSE TO RESTRICTION REQUIREMENT IMPOSED IN APRIL 14, 2005
OFFICE ACTION IN U.S. PATENT APPLICATION NO. 10/633,238**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This responds to the April 14, 2005 Office Action in the above-identified application, in which the Examiner imposed a restriction requirement against claims 1-20 pending in the application, between:

- Claims 1-17, drawn to a centrifuge tube (Group I);
- Claims 18-19, drawn to a kit (Group II); and
- Claim 20, drawn to a method of making a centrifuge tube (Group III).

In response, applicant elects Group I claims 1-17. Such election is WITH TRAVERSE.

The traversal is based on the fact that the stated grounds for the restriction do not comport with the requirements of the 35 USC 121, which requires that:

"[I]f two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions."

The statute therefore requires as a basis for legally permissible restriction that the subject matter of respective claims be both independent and distinct.

Claim 1 is set out below for ease of reference:

"1. A centrifuge tube having a closed distal end, and an open proximal end, with integral hinge elements at opposing sides thereof for facilitating compression flattening of the centrifuge tube."

Claim 18 requires:

"18. A specimen collection kit comprising a centrifuge tube as in claim 1, a cap matably engageable with the proximal open end of the centrifuge tube, and a swab article for specimen collection." (emphasis added)

It is apparent from comparison of claims 1 and 18 that the subject matter of these claims includes as common subject matter the centrifuge tube recited in claim 1.

The Examiner's attention is directed in this respect to the provisions of MPEP Section 802 .01 (Meaning of "Independent" and "Distinct"), which states, inter alia:

"The term 'independent' (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect..."

It is apparent from this provision of the MPEP that the subject matter of Group I representative claim 1 and Group II representative claim 18 is not "independent" within the meaning of 35 USC 121 in the respective claims, and that therefore Groups I and II are NOT properly restricted.

Corresponding lack of basis exists for the restriction requirement between Groups I and III. The Group III claim 20 recites:

"20. A method of making a compressively flattenable centrifuge tube, comprising molding the centrifuge tube with integral hinge elements at opposing sides thereof, wherein said molding comprises extrusion blow molding or rotational molding."

Considering such Group III claim 20 and Group I claim 1, directed to a "centrifuge tube... with integral hinge elements at opposing sides thereof for facilitating compression flattening of the centrifuge tube," it is apparent that the subject matter of claim 20 and claim 1 CANNOT BE CHARACTERIZED as being "unconnected in design, operation or effect" (MPEP Section 802.01). The restriction requirement applied against Groups I and III therefore is improper.

In like manner, the restriction between Group II claims and Group III claims is without proper basis under the criteria mandated by the MPEP.

Group II representative claim 18 requires:

"18. A specimen collection kit comprising a centrifuge tube as in claim 1, a cap matably engageable with the proximal open end of the centrifuge tube, and a swab article for specimen collection." (emphasis added)

Group I representative claim 1 recites:

"1. A centrifuge tube having a closed distal end, and an open proximal end, with integral hinge elements at opposing sides thereof for facilitating compression flattening of the centrifuge tube." (emphasis added)

Group III claim 20 recites:

"20. A method of making a compressively flattenable centrifuge tube, comprising molding the centrifuge tube with integral hinge elements at opposing sides thereof, wherein said molding comprises extrusion blow molding or rotational molding." (emphasis added)

Considering therefore the centrifuge tube recited in claim 1, the recital of which is incorporated in Group II claim 18, and the centrifuge tube recited in Group III claim 20, it again is seen that the subject matter of claim 18 and claim 20 CANNOT BE CHARACTERIZED as being "unconnected in design, operation or effect" (MPEP Section 802.01).

The Examiner has given as his reason for restriction and assertion that the subject matter of the Group II and Group III claims that these claims "have different modes of operation in that the method claims are directed to a manner of making a subcombination element of the claim, which is not seen as relevant¹ to the subcombination of elements associate [sic] with the kit" (emphasis added). This statement is inconsistent - if the method claims are "method of making" claims directed to a subcombination element, then the methodology of such claims necessarily and absolutely is "relevant" to the subcombination. The stated basis therefore establishes a substantive connection between the Group 2 claims directed to the kit, and the Group 3 claim directed to a method of making the centrifuge tube of such kit, and under the MPEP criterion quoted in the preceding paragraph, restriction is improper.

Based on all the foregoing, it is requested that the restriction requirement be withdrawn.

Further, it is pointed out that the subject matter of the respective claims imposes no serious burden of searching on the Examiner, particularly since Group II contains only two claims (claims 18 and 19), and Group III contains only one claim (claim 20).

According to the MPEP section 803:

"[I]f the search and examination of an entire application can be made without serious burden, the examiner must examine

¹ It is noted that relevance is not the applicable standard of 35 USC 121; see MPEP §§ 802 and 802.01.

it on the merits, even though it includes claims to independent or distinct inventions." MPEP §803.

Under the applicable criterion of this MPEP provision, the Examiner is required to submit all claims 1-20 to examination on the merits.

CONCLUSION

Based on the foregoing, the Examiner is requested to reconsider, and on reconsideration to withdraw, the restriction requirement imposed against claims 1-20 in the April 14, 2005 Office Action², and to submit all claims 1-20 to examination on the merits.

If any additional issues remain, the Examiner is requested to contact the undersigned attorney at (919)419-9350 to discuss same, in order that the prosecution of this application is expedited.

Respectfully submitted,



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² If, despite the compelling basis for withdrawal of the restriction requirement, such restriction requirement is nonetheless maintained and made final, applicant affirmatively requests rejoinder of the method claim 20 under the applicable rejoinder provisions of MPEP §821.04 upon confirmation of allowable subject matter in the article claims 1-17 and kit claims 18-19.